510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K131876

1. Date of Submission: 06/08/2013

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: M Series Patient Monitor
Proposed Device Model: M66, M69, M7000, M8000 and M9000
Proposed Device Common Name: Patient Monitor

Regulatory Information:
Classification Name: Monitor, Physiological, Patient;
Classification: II;
Product Code: MHX;
Regulation Number: 21 CFR 870.1025;
Review Panel: Cardiovascular;
Subsequent Product Code:

Product Code	Regulation Number	Classification Name	Panel
DRT	870.2300	Monitor, Cardiac (incl. cardiotachometer & rate alarm)	Cardiovascular
DXN	870.1130	System, Measurement, Blood-pressure, Non-invasive	Cardiovascular
DSK	870.1110	Computer, Blood-pressure	Cardiovascular
DQA	870.2700	Oximeter	Anesthesiology
BZQ	868.2375	Monitor, Breathing Frequency	Anesthesiology
CCK	868.1400	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	Anesthesiology
FLL	880.2910	Thermometer, Electronic, Clinical	General Hospital

Intended Use Statement:

M Series Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.

The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance.

Note: M7000 does not have functions of Invasive Blood Pressure and Carbon Dioxide.

5. Predicate Device Identification

510(k) Number: K100046
Product Name: M Series Patient Monitor
Manufacturer: Guangdong Biolight Meditech Co., Ltd.

510(k) Number: K053269
Product Name: MASIMO SET RAD-8 PULSE OXIMETER
Manufacturer: Masimo Corporation

6. Device Description

The proposed devices, M Series Patient Monitors, M66, M69, M7000, M8000 and M9000, are modification devices to the existed devices, M Series Patient Monitors, M66, M69, M7000, M8000 and M9000 as cleared in K100046 at 04/08/2010.

The proposed devices and the existed devices share same intended use, design principle and technical specifications. The main modification of the proposed devices is adding a SpO2 module, which was designed and manufactured by Masimo Corporation and previously cleared by FDA in **K053269** at 12/21/2005. It is an independent module installed within the patient monitor, without any other modifications, and shall be used with the specified accessories, which are listed in following table.

Table 3-1 Accessories of Masimo SpO2 Module

ITEM	Accessory	Reusable/Disposable	Population	Type
DCI / 2501	SpO_2 Sensor	Reusable	Adult	Clip
DCIP / 2502	SpO_2 Sensor	Reusable	Pediatric	Clip
Neo / 2514	SpO_2 Sensor	Disposable	Infant	Wrap
M-LNC1 / 2523	Extension Cable	N.A.	N.A.	N.A.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 14971:2007 Medical devices -- Application of risk management to medical devices;
IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
IEC 60601-1-2, (Edition 2:2001 with Amendment 1:2004), Medical Electrical Equipment - Part 1-2:

General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests;
ISO 9919:2005: Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-2 Comparison of General and Safety Characteristics

Item		Proposed Devices M Series Patient Monitor	Predicate Devices K100046
Product Code		MHX	Same
Regulation No.		21 CFR 870.1025	Same
Class		Class II	Same
Intended Use		M Series Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance. Note: M7000 does not have functions of Invasive Blood Pressure and Carbon Dioxide	Same
Feature	Display	Colour TFT	Same
	Alarm	Visual and audio alarming	Same
Electrical Safety		The proposed devices were tested to demonstrate to comply with IEC 60601-1.	Same
EMC		The proposed devices were tested to demonstrate to comply with IEC 60601-1-2	Same
Patient-contact Material		ECG Electrode: Conductive adhesive SpO2 Sensor: Silicone NIBP Cuff: Polyester fibre $EtCO_2$ Sensor: PVC Temperature Probe: PVC	Same
Level of Concern of the Software		Major	Same
Label and Labeling		Conforms to FDA Regulatory Requirements	Same

Table 3-3 Comparison of ECG, NIBP, TEMP, RESP and SpO2 Characteristics

Item		Proposed Devices M Series Patient Monitor	Predicate Devices K100046
ECG Lead Mode		5-leads ECG input / 3-leads ECG input	Same
ECG CMRR		MON ≥105dB / OPS ≥105dB	Same
ECG Sweep speed		12.5mm/s, 25mm/s, 50mm/s	Same
HR Range		10~350 bpm	Same
HR Accuracy		±1% or ±1 bpm, whichever is greater	Same
NIBP Method		Oscillometric	Same
NIBP Measurement Unit		mmHg / kPa	Same
NIBP Measurement Range	Adult	10-270 mmHg	Same
	Pediatric	10-235 mmHg	Same
	Neonatal	10-135 mmHg	Same
NIBP Accuracy		(Static) ±2% or ±3 mmHg, whichever is greater (Clinical) ±5 mmHg average error ≤ 8 mmHg standard deviation	Same
TEMP Range		0.0~50.0°C	Same
TEMP Accuracy		At 45.1°C~50.0°C, ±0.2°C (exclusive of probe) At 25.0°C~45.0°C, ±0.1°C (exclusive of probe) At 0.0°C~24.9°C, ±0.2°C (exclusive of probe)	Same
RESP Method		Impedance variation between RA-LL (R-F)	Same
RESP Measurement Range		0~150 rpm	Same
RESP Accuracy		±2 rpm	Same
BLT SpO2 Module			
SpO2 Range		0~100%	Same
SpO2 Accuracy		At 70~100%, ±2% At 0~69%, unspecified	Same
PR Range		25~250 bpm	Same
PR Accuracy		±1% or ±1 bpm, whichever is greater	Same
Nellcor SpO2 Module			
SpO2 Range		1~100%	Same
SpO2 Accuracy		At 70~100%, ±2 digits (Adult) At 70~100%, ±3 digits (Neonate) At 70~100%, ±2 digits (Low Perfusion) At 0~69%, unspecified	Same
PR Range		20~250 bpm	Same
PR Accuracy		±3 digits	Same

Table 3-4 Comparison of Masimo SpO2 Characteristics

Item	Proposed Devices M Series Patient Monitor	Predicate Devices K053269	Predicate Devices K100046
SpO2 Module	MASIMO Module	Same	Similar
SpO2 Range	1~100%	Same	Same
SpO2 Accuracy	At 70~100%: ±2% (adult/pediatric, non-motion conditions) At 70 ~ 100%: ±3% (neonate, non-motion conditions) At 70 ~100%: ±3% (motion conditions) At 0~69%, unspecified	Same	Similar
PR Range	25~240 bpm	Same	Similar
PR Accuracy	±3 bpm (non-motion conditions) ±5 bpm (motion conditions)	Same	Similar
PI Range	0.02 ~ 20.0%	Same	NA

Table 3-5 Comparison of IBP and $EtCO_2$ Characteristics (Inapplicable to M7000)

Item	Proposed Devices M Series Patient Monitor	Predicate Devices K100046
IBP Measurement Range	-50 ~ +300 mmHg	Same
IBP Sensitivity of transducer	5uV/V/mmHg, 2%	Same
IBP Accuracy	± 4mmHg or 4%, whichever is greater	Same
$EtCO_2$ Method	Infrared Absorption	Same
$EtCO_2$ Mode	Main Stream / Side Stream	Same
$EtCO_2$ Measurement Range	0 ~ 19.7 %(0 ~ 150 mmHg)	Same
$EtCO_2$ Accuracy	0 ~ 40 mmHg, ±2 mmHg 41 ~ 70 mmHg, ±5% of reading 71 ~100 mmHg, ±8% of reading 101 ~ 150 mmHg, ±10% of reading	Same

The proposed device has a Masimo SpO2 Module, while the predicate device M Series Patient Monitor (K100046) doesn't have. The Masimo SpO2 Module was designed and manufactured by Masimo Corporation and previously cleared by FDA in **K053269**. And SpO2 and pulse rate accuracy of the proposed device with Masimo SpO2 Module has been verified comply with the declaration of specification. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The proposed devices, M Series Patient Monitors, are determined to be Substantially Equivalent (SE) to the predicate devices, M Series Patient Monitors (K100046), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 27, 2014

Guangdong Biolight Meditech Co.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K131876
Trade/Device Name: M Series Patient Monitor models M66, M69, M7000, M8000, and M9000
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Monitor
Regulatory Class: Class II
Product Code: MHX
Dated: January 29, 2014
Received: January 30, 2014

Dear Ms. Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131876
Device Name: M Series Patient Monitor

Indications for Use:

M Series Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of adult, pediatric and neonatal patient as listed below:

Parameters	M66	M69	M7000	M8000	M9000
ECG	x	x	x	x	x
Heart Rate	x	x	x	x	x
Respiration Rate (RESP)	x	x	x	x	x
Pulse Oxygen Saturation (SpO2)	x	x	x	x	x
Non-Invasive Blood Pressure (NIBP)	x	x	x	x	x
Invasive Blood Pressure (IBP)	x	x	--	x	x
Carbon Dioxide (CO2)	x	x	--	x	x
Temperature (TEMP)	x	x	x	x	x

The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

It is not intended for helicopter transport or hospital ambulance.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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